

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

CARMEN PURL, M.D., *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES, *et al.*,

Defendants.

No. 2:24-cv-228-Z

**DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION TO DISMISS OR, IN
THE ALTERNATIVE, FOR SUMMARY JUDGMENT**

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INTRODUCTION

As Defendants’ prior briefing explains, this case is precisely the type that Article III is intended to “screen[] out.” *See FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 381 (2024). Although Dr. Carmen Purl undoubtedly opposes the rule she seeks to challenge, *see HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32976 (Apr. 26, 2024) (“Rule”), there is no indication that the Rule is actually injuring her in any cognizable way or that it will ever do so—a fundamental condition of Article III standing. Indeed, despite filing four substantive briefs and three declarations in this matter, Dr. Purl *still* has not cured the evidentiary defects that Defendants have repeatedly highlighted. The absence of any evidence of a cognizable injury attributable to the Rule is dispositive of the parties’ cross-motions: This Court lacks jurisdiction and should dismiss this case accordingly.

ARGUMENT

I. Dr. Purl lacks Article III standing.

In her opposition brief, *see* Pls.’ Br. in Opp. to Defs.’ MTD or, in the Alternative, for Summ. J. (“Pls.’ Opp.”), ECF No. 66, Dr. Purl insists that she has done enough to establish Article III standing to challenge the Rule. But her arguments on this score are unpersuasive. Although Defendants have already rebutted most of these arguments in prior briefing, *see* Defs.’ Br. in Supp. of MTD or, in the Alternative, for Summ. J. (“Defs.’ Br.”) at 11–16, EF No. 40; Defs.’ Opp. to Pls.’ Mot. for Summ. J. (“Defs.’ Opp.”) at 2–4, ECF No. 70, a few points warrant a response.

First, Dr. Purl suggests that she need not show an actual or imminent injury attributable to the Rule to establish Article III standing, because it is enough that she, as a covered entity, “is an object” of the Rule’s requirements, even if only in a purely abstract sense. *See* Pls.’ Opp. 9. But the line of cases she invokes simply explains that standing is typically easier to establish where a regulation requires the plaintiff, rather than someone else, to act. *See, e.g., All. for Hippocratic Med.*, 602 U.S. at 382. Those cases do not support the proposition that an uninjured plaintiff has standing merely by dint of being a

member of a community regulated by a challenged action. Indeed, it “would fly in the face of Article III’s injury-in-fact requirement” to hold, as Dr. Purl contends, that a plaintiff has standing to challenge a “regulation in the abstract,” “apart from any concrete application that threatens imminent harm” to her interests. *Summers v. Earth Island Inst.*, 555 U.S. 488, 494 (2009). And despite her claims to the contrary, she has submitted no competent evidence that the Rule materially affects her operating costs—*e.g.*, that it will change how much time it takes to respond to requests for information from state law enforcement agencies, or alter the total cost of the update to her notice of privacy practices already required by a separate regulation. *See* Defs.’ Br. 15; Defs.’ Opp. 3–4.

Second, Dr. Purl maintains that, for purposes of analyzing standing, this Court must accept her portrayal of how the Rule works, no matter how implausible, *see* Defs.’ Opp. 2, because how she depicts the Rule is also relevant to the merits of her claims, *see* Pls.’ Opp. 8. But this Court should not blindly accept a plaintiff’s facially inaccurate reading of a rule in determining whether it has jurisdiction simply because the plaintiff relies on that reading both to concoct standing and to argue the merits of her claims. *See, e.g., Ariz. All. for Retired Ams. v. Mayes*, 117 F.4th 1165, 1178 (9th Cir. 2024) (rejecting standing theory that rested on “an implausible reading” of the challenged law); *Sch. of the Ozarks, Inc. v. Biden*, 41 F.4th 992, 998 (8th Cir. 2022) (rejecting standing theory “based on a misunderstanding” of the challenged law).

Third, in her response brief, Dr. Purl unveils for the first time two new theories of harm. As an initial matter, these theories are untimely and have thus been forfeited. *See Ctr. for Bio. Diversity v. EPA*, 937 F.3d 533, 542 (5th Cir. 2019). But they are also meritless. Take Dr. Purl’s “worries” about how her patients might be “endangered” if other covered health care providers do not report suspected abuse or respond to requests for information because of the Rule. *See* Pls.’ Opp. 6, 38. That theory of harm fails for a host of reasons, not least because it relies on multiple layers of speculation about how unknown third parties might act in a hypothetical situation, and how those theoretical

actions could impact her patients. *See, e.g., Cent. & S. W. Servs., Inc. v. EPA*, 220 F.3d 683, 701 (5th Cir. 2000) (“[Plaintiff’s] subjective fears and speculative string of events cannot possibly serve as the basis for standing.”). Dr. Purl cannot establish standing based “on speculation about the unfettered choices” of third parties not before the court. *See All. for Hippocratic Med.*, 602 U.S. at 383 (citation omitted); *accord Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 413 (2013) (refusing “to endorse standing theories that require guesswork as to how independent decisionmakers will exercise their judgment”). Nor can she premise standing on her *patients’* alleged injuries, even if they weren’t speculative. *See All. for Hippocratic Med.*, 602 U.S. at 393 n.5 (rejecting doctors’ attempt to “shoehorn themselves into Article III standing simply by showing that their patients ... may suffer future injuries”). Equally unavailing are Dr. Purl’s “worries” that other covered health care providers or business associates may not be willing to share protected health information with her (or receive it from her) because of the Rule, *see* Pls.’ Opp. 6, 37, which again rest on sheer speculation about how third parties might act.

Lastly, Dr. Purl suggests that she already established standing for the life of this lawsuit because this Court found that Dr. Purl’s compliance-cost theory of harm sufficed to establish standing at the preliminary-injunction stage. *See* Pls.’ Opp. 10–11. But that’s doubly incorrect. This Court is not bound at summary judgment by any conclusions, legal or factual, that it made at the preliminary-injunction stage. *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981). That’s because “a preliminary injunction is customarily granted on the basis of procedures that are less formal and evidence that is less complete than” at later stages of a case. *Id.* Indeed, “the manner and degree of evidence required to show standing” at summary judgment is greater than at the preliminary-injunction stage. *Speech First, Inc. v. Fenves*, 979 F.3d 319, 329–30 (5th Cir. 2020). So Dr. Purl cannot simply hang her hat on this Court’s prior standing analysis, but now must present evidence that sufficiently substantiates her theories of harm for purposes of summary judgment. And as explained, *see* Defs.’ Br. 12–16; Defs.’ Opp. 2–4, the evidence she has submitted is wanting.

II. At a minimum, any relief should be narrowly tailored.

Dr. Purl maintains that this Court should either vacate or enjoin the entire Rule universally. *See* Pls.’ Opp. 32. But across two briefs, she has not justified those far-reaching remedies or explained how, in this case, either would comport with fundamental constraints on the Court’s remedial authority. Instead, the upshot of her argument is simple: Because vacatur is the usual remedy in APA cases within the Fifth Circuit, this Court should reflexively vacate the Rule universally, or, all else being equal, enjoin it nationwide, without paying mind to the consequences of those sweeping remedies or whether they are necessary to provide Dr. Purl complete relief. But that would be misguided. As explained, *see* Defs.’ Opp. 4–11, neither universal vacatur nor a nationwide permanent injunction of the Rule are required, necessary, or justifiable, and Dr. Purl’s contrary arguments are unpersuasive.

First, Dr. Purl suggests that this Court should universally vacate the Rule regardless of whether that relief is necessary to redress her asserted injuries. *See* Pls.’ Opp. 32–33. But it is this Court’s constitutional obligation to ensure that any remedy it enters is narrowly “tailored to redress” Dr. Purl’s “particular injury,” *Gill v. Whitford*, 585 U.S. 48, 72–73 (2018)—an obligation reinforced by the equitable principle that a remedy be no broader “than necessary” to provide a plaintiff “complete relief,” *Madsen v. Women’s Health Ctr., Inc.*, 512 U.S. 753, 765 (1994); *accord United States v. Texas*, 599 U.S. 670, 702 (2023) (Gorsuch, J., joined by Thomas and Barrett, JJ., concurring in the judgment) (“*Any remedy ... must not be more burdensome to the defendant than necessary to redress the complaining parties.*” (cleaned up with emphasis added)). Dr. Purl does not contend that the APA uprooted or modified those constitutional or equitable limits on this Court’s remedial authority. Nor does she dispute that vacatur, like all equitable remedies, is subject to them.¹ *See, e.g., Cargill v. Garland*,

¹ *See, e.g., Texas*, 599 U.S. at 702 (Gorsuch, J., joined by Thomas and Barrett, JJ., concurring in the judgment) (explaining that, if there is a power to vacate agency action under § 706, it is an “equitable power”); *Black Warrior Riverkeeper, Inc. v. U.S. Army Corps of Eng’rs*, 781 F.3d 1271, 1290 (11th Cir. 2015) (“Undeniably, vacatur [of agency action] is ‘equitable relief.’” (citation omitted)).

57 F.4th 447, 472 (5th Cir. 2023) (explaining that any remedy in an APA case must be narrowly tailored). And so whether or not vacatur has been deemed a “proper” remedy in other cases, it is still Dr. Purl’s burden to show that, in *this* case, universal vacatur would be consistent with both constitutional and equitable remedial principles. *Feds for Med. Freedom v. Biden*, 63 F.4th 366, 389 (5th Cir. 2023) (“[At the merits stage], the plaintiffs will have to *prove* that whatever [relief] they request is broad enough to protect against their proven injuries and no broader.”). But Dr. Purl offers no argument or evidence on that score. Thus, there is nothing in this record on which the Court can conclude that universal vacatur is necessary—or that a party-specific remedy would be inadequate—to provide Dr. Purl complete relief.

Second, although several courts—including another court within this District—are presently reviewing other challenges to the Rule, Dr. Purl would have this Court brush that consideration aside and universally vacate the Rule anyways. *See* Pls.’ Opp. 32–33. But that would disregard cases like *Louisiana v. Becerra*, 20 F.4th 260 (5th Cir. 2021), which asked the “question ... whether one district court should make a binding judgment for the entire country.” *Id.* at 263. There, the Fifth Circuit said no, principally because “[o]ther courts” were simultaneously “considering the[] same issues,” the “ultimate resolution” of which would “benefit from the airing of competing views” among sister courts. *Id.* at 263–64. So too here. And that this case is now at the merits stage does not mean this Court should toss aside basic principles of judicial comity and restraint in determining a proper remedy, as Dr. Purl seems to suggest. In fact, the opposite is true. *See, e.g., Texas*, 599 U.S. at 703 (Gorsuch, J., joined by Thomas and Barrett, JJ., concurring in the judgment) (“At a minimum, . . . district courts must carefully consider” the effects of vacatur “before doling [it] out,” including that “vacatur can stymie the orderly [judicial] review of important questions.”); *Louisiana*, 20 F.4th at 264 (“[This] is an issue of great significance currently being litigated throughout the country. Its *ultimate* resolution will benefit from the airing of competing views in our sister circuits.” (cleaned up with

emphasis added)); *see also, e.g., GBX Assocs., LLC v. United States*, 2022 WL 16923886, at *17 (N.D. Ohio Nov. 14, 2022) (“Ordering universal relief in the instant action ... would inhibit the ability of other federal courts to address the validity of [the challenged action] The Court declines to take this path” to “promote[] respect for our fellow federal courts and the healthy development of the law.”); *Kentucky v. Fed. Highway Admin.*, 728 F. Supp. 3d 501, 526 (W.D. Ky. 2024) (lamenting how the 21 plaintiff states were provided the very relief they originally sought because an out-of-circuit district court decided to universally vacate the challenged rule in a separate action).

Third, Dr. Purl at least concedes that universal vacatur is not *required* to remedy an APA violation, as she argued in her opening brief. In backpedaling, however, she suggests that the only alternative is an equitable remedy that the Fifth Circuit has described as “remand without vacatur.” *See* Pls.’ Opp. 33. But that’s incorrect. As the Fifth Circuit explained in *Cargill*, there are several remedies “more limited” than vacatur, including “injunctive” relief, that may be “appropriate” to redress an APA violation. *See* 57 F.4th at 472. So contrary to Dr. Purl’s suggestion, if this Court were to find that the Rule violates the APA, it is not stuck choosing between universally vacating the Rule or remanding the matter to the Department of Health and Human Services (“HHS”) without vacatur.

At any rate, Dr. Purl has not rebutted Defendants’ argument that remand without vacatur would be the proper remedy if this Court were to find that the Rule is arbitrary and capricious. As explained, *see* Defs.’ Opp. 7–8., such relief is “generally appropriate when there is at least a serious possibility that the agency will be able to substantiate its decision given an opportunity to do so” and where vacatur would be “disruptive.” *Texas v. United States*, 50 F.4th 498, 529 (5th Cir. 2022). But in opposing remand without vacatur, Plaintiffs offer only the *ipse dixit* that any flaws in the Rule “cannot be shored up” by HHS’s further consideration. *See* Pls.’ Opp. 33. But why not? If the flaw were that HHS did not consider an issue or adequately explain its actions, *see* Compl. ¶¶ 131–38, ECF No. 1, that could be remedied on remand without resorting to vacatur, as the Fifth Circuit has found. *See*

Tex. Ass'n of Mfrs. v. U.S. Consumer Prod. Safety Comm'n, 989 F.3d 368, 383, 389–90 (5th Cir. 2021) (remanding without vacatur to allow consideration of an issue that the agency failed to address); *Cent. & S. W. Servs.*, 220 F.3d at 692, 702 (remanding without vacatur to allow the agency to explain its actions, and holding that “failure to explain [an action] does not require vacatur”).

Vacatur would also be disruptive, not only impinging upon the review of other challenges to the Rule, *see supra* 5–6, but unnecessarily disrupting the operations of covered entities that may have modified their practices to comply with the Rule and would have to undo those changes if the Rule were vacated. *See* Defs.’ Opp. 8. In response, Dr. Purl does not pretend that the sweeping remedy she requests would not disrupt other covered entities’ operations. In fact, that is precisely one of the *justifications* she offers for universal vacatur. *See* Pls.’ Opp. 37–38 (requesting universal vacatur to constrain other covered entities). At bottom, Dr. Purl maintains that she and her clinic are entitled to universal vacatur of the entire Rule, regardless of the consequences for everyone else. But that is not how an equitable remedy like vacatur works. *See supra* 4–5.

Fourth, in trying to justify her request for a nationwide injunction, Dr. Purl ignores a fundamental problem: Her claims simply don’t call for one. As explained, *see* Defs.’ Opp. 10, an injunction must be “limited to the inadequacy that produced” the plaintiff’s injury. *Lewis v. Casey*, 518 U.S. 343, 357 (1996); *accord Swann v. Charlotte-Mecklenburg Bd. of Educ.*, 402 U.S. 1, 16 (1971). Yet the injunction Dr. Purl requests would enjoin applications of the Rule that she does not contend are unlawful and that are unrelated to the injuries she alleges. So regardless of whether Dr. Purl thinks a nationwide injunction would be a good idea, such a needlessly broad remedy would conflict with well-established equitable principles.

Also, Dr. Purl suggests that this Court should enjoin the Rule nationwide because, if other covered health care providers and business associates comply with the Rule, they will “likely” be unwilling to share protected health information with her (or receive it from her), which would be

detrimental to her business. *See* Pls.’ Opp. 37. It is unclear why this would justify nationwide relief when the vast majority of health care providers will presumably never interact with Dr. Purl’s small, rural clinic in Dumas, Texas. But regardless, this argument rests on sheer speculation about how third parties may act, which can form neither the basis of Article III standing nor irreparable injury. *See Louisiana v. Biden*, 55 F.4th 1017, 1034 (5th Cir. 2022) (“[Irreparable harm] must be more than speculative; there must be more than an unfounded fear on the part of the applicant.” (citation omitted)); *accord, e.g., John Doe Co. v. CFPB*, 849 F.3d 1129, 1134–35 (D.C. Cir. 2017) (rejecting theory of irreparable harm that depended on “speculation about how third parties might” act). And speculation aside, this Court should decline to endorse such a boundless theory of its equitable power.

Finally, Dr. Purl all but ignores severability. She does not dispute that the Rule’s severability clauses should be “adhere[d] to” absent “extraordinary circumstances,” *see* Defs.’ Opp. at 9 (quoting *Texas v. United States*, 126 F.4th 392, 419 (5th Cir. 2025)), and points to no such circumstances here. Nor does she attempt to show that the Rule’s other provisions “could not function sensibly” if any vacatur were limited to only the provisions that supposedly harm Dr. Purl, *see id.* (quoting *Tenn. Walking Horse Nat’l Celebration Ass’n v. USDA*, 2025 WL 360895, at *13 (N.D. Tex. Jan. 31, 2025)), instead halfheartedly attempting to shift that burden onto Defendants, *see* Pls.’ Opp. 38; *see also Nat’l Ass’n of Mfrs. v. SEC*, 105 F.4th 802, 815–16 (5th Cir. 2024) (requiring plaintiffs to show that a rule is inseverable). The Court should reject Dr. Purl’s invitation to disregard these black-letter principles.

CONCLUSION

The Court should dismiss this case for lack of subject-matter jurisdiction. But if the Court enters summary judgment in Dr. Purl’s favor, it should narrowly tailor any relief so as to redress only her actual injuries.

Dated: March 17, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

On March 17, 2025, I electronically submitted the foregoing document with the Clerk of Court for the U.S. District Court, Northern District of Texas, using the Court's electronic case filing system. I hereby certify that I have served all parties electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

/s/ Jody D. Lowenstein
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